07-19-04

1fw



Express Mail No.: EV475140872US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Muller et al.

Confirmation No.:

To Be Assigned

Serial No.:

10/748,085

Group Art Unit:

1614

Filed:

December 29, 2003

Examiner:

To Be Assigned

For:

FLUOROALKOXY-SUBSTITUTED

Attorney Docket No.: 9516-084-999

1,3-DIHYDRO-ISOINDOLYL COMPOUNDS AND THEIR PHARMACEUTICAL USES

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97 & §1.56

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent and Trademark Office of all references coming to the attention of Applicant or his attorneys which are or may be related to patentability of the claimed invention, Applicant hereby directs the Examiner's attention to references **B01** to **B06** and **C01** to **C36**, which are listed on the accompanying revised PTO Form 1449.

Legible copies of listed references **B01** to **B06** and **C01** to **C36** are provided herewith. Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application. Identification of the listed references is not to be construed an admission by Applicant or his attorneys that such references are available as "prior art" against the subject application.

Pursuant to 37 C.F.R. § 1.97(b), it is estimated that no fee is due. However, if a fee is deemed to be due, please charge the required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

Date: July 15, 2004

tul M /m

35,203

Anthony M. Insogna

(Reg. No.)

JONES DAY

12750 High Bluff Drive, Suite 300 San Diego, California 92130 (858) 314-1200

Bv

Nicholas J. DiCeglig, Jr

21,615 Pog. No.)

JONES DAY

222 East 41st Street

New York, New York 10017-6702

(212) 326-3939

Pursuant to 37 C.F.R. § 1.97(b), it is estimated that no fee is due. However, if a fee is deemed to be due, please charge the required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

Date: July 15, 2004

tul M June

35,203

Anthony M. Insogna

(Reg. No.)

JONES DAY

12750 High Bluff Drive, Suite 300 San Diego, California 92130 (858) 314-1200

_

olas I DiCaslik Ir

JONES DAY

222 East 41st Street

New York, New York 10017-6702

(212) 326-3939

Express Mail No.: EV475140872US

Sheet 1 of 2

			ATTY DOCKET NO.		APPLICATION NO							
			9516-084-999		10/748,085							
LIST OF	EFE	RENCES CITED BY	APPLICANT									
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	: vc,	(Use several sheets if t	necessary)	Muller et al.								
/0		` '	FILING DATE GROUP									
JUL 1	5 2004	٤	12/29/03		1614							
		ę.	***C ***		1,				-			
PATENT	& TRALL	7	U.S. PA	TENT DOCUM	ENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	N	АМЕ	CLASS	SUBCLASS	FILING D				
				<u> </u>			SOUCEASS	II AITROI	MAIL			
•												

			*			_1	1					
-			FOREIGN	PATENT DOC	UMENTS							
	DOCUMENT NUMBER DATE COUNTRY CLASS SUBCLASS TRANSLATION											
						7 02.100	TODECARGO	YES	NO			
	B01	WO 02/16305	2/28/02	PCT								
	B02	WO 01/90076	11/29/01	PCT								
	B03	WO 01/34606	5/17/01	PCT								
	B04	WO 01/34603	5/17/01	PCT								
	B05	WO 97/23457	7/3/97	PCT								
	B06	DD 298 389	10/27/83	East Germany								
									-			
		OTHER REFERE	ENCES (Incl	uding Author, Tit	le, Date, Pertineni	t Pages, I	Etc.)					
	C01	Baughman et al., 1990,		or necrosis factor by	alveolar macrophages	of patients	with sarcoide	osis," J. La	ab.			
	G02	Clin. Med. 115(1): 36- Beavo et al., 1990, "Prir		f cyclic nucleotide ph	osphodiasterasa isozu	mac and th	a design of so	laativa				
	C02	inhibitors," Trends Phar	macol. Sci. 11	(4): 150-155	iospilodiesierase isozy	ines and th	ie design of se	rective				
	C03	Beckett et al., 1996, Dru	ig Discovery To	oday 1:16-26					•			
	C04	Berge et al., 1977, "Pha		<u> </u>								
	C05	Bertolini et al., 1986, "S		one resorption and inh	nibition of bone forma	tion in vitre	by human tu	mour necr	osis			
	C06	factors," Nature 319(6053): 516-518 Bissonnette et al., 1989, "Pulmonary inflammation and fibrosis in a murine model of asbestosis and silicosis. Possible role										
	ļ	of tumor necrosis factor,'	'Inflammation	13(3): 329-339								
	C07	Clouse et al., 1989, "Mo T cell clone," J. Immuno			deficiency virus-1 exp	ression in	a chronically	infected hu	ıman			
	C08	Dezube et al., 1990, "Pe			with cancer," Lance	t 335(869	0):662					
	C09		Duh et al., 1989, "Tumor necrosis factor alpha activates human immunodeficiency virus type 1 through induction of nuclear									
	C10	factor binding to the NF-										
	CIO	Elliott et al., 1995, "TNF alpha blockade in rheumatoid arthritis: rationale, clinical outcomes and mechanisms of action," Int. J. Immunopharmacol. 17(2): 141-145										
	CH	Ferrai-Baliviera et al., 1989, "Tumor necrosis factor induces adult respiratory distress syndrome in rats," Arch. Surg.										
	C12	Folks et al., 1989, "Tumor necrosis factor alpha induces expression of human immunodeficiency virus in a chronically										
		infected T-cell clone," Proc. Natl. Acad. Sci. USA 86(7): 2365-2368										
	C13 Grau et al., 1989, "Tumor necrosis factor and disease severity in children with falciparum malaria," N. Engl. J. Med. 320(24):1586-91											
	C14											
1		AMP-agonist hyporespor	siveness" I A	llergy Clin Immun	ol 70(6): 452-457			_				

Express Mail No.: EV475140872US

Sheet 2 of 2

	Sheet 2 Of 2					
C15	Guay et al., 2002, "Discovery of L-791,943: a potent, selective, non emetic and orally active phosphodiesterase-4 inhibitor," Bioorg. Med. Chem. Lett. 12(11): 1457-1461					
C16	Hanifin et al., 1996, "Type 4 Phosphodiesterase Inhibitors Have Clinical and in vitro Anti-inflammatory Effects in Atopic Dermatitis," J. of Investigative Dermatology 107(1):51-56					
C17	Hatzelmann et al., 2001, "Anti-inflammatory and immunomodulatory potential of the novel PDE4 inhibitor roflumilast in vitro," J. Pharmacol. Exp. Ther. 297(1):267-279					
C18	Hinshaw et al., 1990, "Survival of primates in LD100 septic shock following therapy with antibody to tumor necrosis factor (TNF alpha)," Circ. Shock 30(3):279-292					
C19	Holler et al., 1990, "Increased serum levels of tumor necrosis factor alpha precede major complications of bone marrow transplantation," Blood 75(4): 1011-1016					
. C20	Houslay et al., 1998, "The multienzyme PDE4 cyclic adenosine monophosphate-specific phosphodiesterase family: intracellular targeting, regulation, and selective inhibition by compounds exerting anti-inflammatory and antidepressant actions," Adv. Pharmacol. 44:225-342					
. C21	Huang et al., 2001, "The Next Generation of PDE4 inhibitors," Curr. Opin. Chem. Biol. 5:432-438					
. C22	Johnson et al., 1989, "Tumors producing human tumor necrosis factor induced hypercalcemia and osteoclastic bone resorption in nude mice," Endocrinology 124(3):1424-1427					
C23	List et al., 1990, "The myelodysplastic syndromes: biology and implications for management," J. Clin. Oncol. 8(8):1424-1441					
- C24	Lowe et al., 1992, Drugs of the Future 17(9):799-807					
C25	Millar et al., 1989, "Tumour necrosis factor in bronchopulmonary secretions of patients with adult respiratory distress syndrome," Lancet 2(8665):712-714					
C26	Monte et al., 1990, "Productive human immunodeficiency virus-1 infection of megakaryocytic cells is enhanced by tumor necrosis factor-alpha," Blood 79(10): 2670-2679					
C27	Piguet et al., 1990, "Requirement of tumour necrosis factor for development of silica-induced pulmonary fibrosis," Nature 344(6263):245-247					
C28	Poli et al., 1990, "Tumor necrosis factor alpha functions in an autocrine manner in the induction of human immunodeficiency virus expression," Proc. Natl. Acad. Sci. USA 87(2): 782-785					
C29	Poli et al., 1992, "The effect of cytokines and pharmacologic agents on chronic HIV infection," AIDS Res. Hum. Retroviruses 8(2):191-197					
C30	Rice et al., 1989, "An inducible endothelial cell surface glycoprotein mediates melanoma adhesion," Science 246(4935):1303-1306					
C31	Shealy et al., 1968, "Synthesis of D- and L-thalidomide and related studies," J. Pharm. Sci. 57(5):757-764					
C32	Shealy et al., 1965, "D- and L-thalidomide," Chem. Ind. 24:1030-1031					
C33	Tierney et al., ed., 1998, Curr. Med. Diag. Treat. 37th ed., 499					
C34	Tracey et al., 1987, "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," Nature 330(6149):662-664					
C35	Verghese et al., 1995, "Differential regulation of human monocyte-derived TNF alpha and IL-1 beta by type IV cAMP-phosphodiesterase (cAMP-PDE) inhibitors," J. Pharmacol. Exp. Ther. 272(3): 1313-1320					
C36	Van Dullemen et al., 1995, "Treatment of Crohn's disease with anti-tumor necrosis factor chimeric monoclonal antibody (cA2)," Gastroenterology 109(1):129-135					

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.